NATIONAL GUIDELINE CLEARINGHOUSE™ (NGC) GUIDELINE SYNTHESIS

TOBACCO USE CESSATION

GUIDELINES BEING COMPARED

1. **Public Health Service (PHS)**. Treating tobacco use and dependence: 2008 update. Rockville (MD): 2008 May. 257 p.
2. **University of Michigan Health System (UMHS)**. Smoking cessation. Ann Arbor (Michigan): University of Michigan Health System, 2006. 12 p. [1 reference]
3. **U.S. Preventive Services Task Force (USPSTF)**. Counseling and interventions to prevent tobacco use and tobacco-caused disease in adults and pregnant women: U.S. Preventive Services Task Force reaffirmation recommendation statement. Ann Intern Med 2009 Apr 21;150(8):551-5. [7 references]

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AREAS OF AGREEMENT AND DIFFERENCE

A direct comparison of recommendations presented in the above guidelines for tobacco use cessation is provided below.

Areas of Agreement

Initial Interventions

All three guidelines recommend a variation of the "Five A" behavioral counseling framework of asking (identifying users), advising (urging users to quit), assessing (determining users' willingness to quit), assisting (through counseling or drug therapy), and arranging for follow-up. UMHS recommends an updated variation of this framework known as the "3-A's and Refer" model. This model recommends that if, during assessment, it is determined that the patient is interested in quitting within 30 days, he or she should be referred to a Tobacco Treatment Specialist or other tobacco cessation program. They do, however, also provide treatment recommendations for physicians who choose to treat the patient rather than refer him or her.

The guidelines agree that all patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. The groups recommend that physicians advise all tobacco users identified during screening to seriously consider making a quit attempt and that advice should be "clear," "strong," and "personalized" and should include a discussion of the health benefits of quitting, self-help materials, and referral to community groups, if necessary. After being assessed for willingness to quit, each of the guidelines also agrees that patients who do not wish to quit should receive motivational interventions (e.g., the 5 R's: relevance, risks, rewards, roadblocks, and repetition).

Counseling and Behavioral Therapies

There is overall agreement that tobacco users who are willing to quit should have access to some form of counseling, including intensive counseling if desired. According to PHS, counseling is most effective when delivered by a variety of clinician types and in multiple formats, and that proactive telephone counseling (quitlines), group counseling, and individual counseling are effective. Similar to PHS, USPSTF also notes that various primary care clinicians may deliver effective interventions. PHS and USPSTF agree that counseling interventions should include both practical counseling (problem solving/skills training) and the provision of support and encouragement. UMHS notes that when providing counseling, health care providers should be aware that barriers to smoking cessation include, but are not limited to, severe withdrawal during previous quit attempts, the presence of other smokers in the home or workplace, stressful life circumstances, psychiatric co-morbidities (i.e., depression, alcoholism), multiple quit attempts, and low motivation.

The dose-response relationship between treatment intensity and abstinence from tobacco use is emphasized by all three groups. They agree that counseling as brief as three minutes can be effective in smoking cessation, but that intensive interventions are more effective than less intensive interventions and should be used whenever possible. USPSTF notes that quit rates seem to plateau after 90 minutes of total counseling contact time. With regard to frequency, there is overall agreement that multiple counseling sessions increase abstinence rates. PHS notes that, if possible, clinicians should strive to meet four or more times with individuals quitting tobacco use. UMHS similarly notes that intensive

counseling (frequently defined as a minimum of weekly meeting for the first 4 to 7 weeks of cessation) significantly enhances cessation rates.

Pharmacologic Therapy

Recommendations regarding pharmacologic therapy are similar. All three groups cite the following FDA-approved therapies as effective: NRT (nicotine gum, patch, inhaler, nasal spray, and lozenge), bupropion, and varenicline. Nortriptyline and clonidine (non-FDA approved agents) are recommended as second-line treatments by PHS and UMHS.

PHS and UMHS address combining NRTs for improved efficacy. According to PHS, combining the nicotine patch long-term (>14 weeks) with a self-administered form of NRT (gum or nasal spray) is more efficacious than a single form of NRT. The combination of the nicotine patch and the nicotine inhaler is also cited as effective by PHS. UMHS, however, notes that, given the additional cost of dual therapies and limited benefit, combining NRT is best reserved for highly addicted smokers with several previous failed quit attempts.

With regard to combining NRT and non-nicotine medications, PHS recommends the combination of the nicotine patch and bupropion SR, noting that it is the only combination approved by the FDA for smoking cessation. UMHS does not provide a formal recommendation but notes that for smokers who have previously been unsuccessful, one randomized study showed higher success rates for both bupropion alone or in combination with the nicotine patch, compared to nicotine patch alone.

There are some disagreements on the use of drug therapy in pregnant women and in children and adolescents. Refer to Areas of Difference below.

Pregnant Women

The guideline groups agree that pregnant women who smoke should be offered intensive counseling. According to UMHS, if intensive counseling is not possible, brief in-office counseling still has a beneficial effect and should be offered. USPSTF specifies that the counseling should be augmented with messages and self-help materials tailored for pregnant smokers. There is overall agreement that while abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits.

Counseling of Children and Adolescents

PHS and UMHS agree that there is evidence to support the effectiveness of counseling interventions to promote smoking cessation in adolescents. UMHS states that the evidence is less robust than for adults, but that some studies do demonstrate that smoking cessation counseling in the primary care setting can improve adolescent smokers' quit rates. USPSTF plans to issue a separate recommendation statement about counseling to prevent tobacco use in nonpregnant adolescents and children.

Recommendations regarding pharmacological interventions in adolescents differ. Refer to Areas of Difference below.

Other Special Populations

PHS and UMHS agree that special populations can benefit from many of the same treatments as the general population, but that treatment can be improved by recognizing the problems or concerns of the individual.

Follow-Up (Prevention of Relapse)

There is overall agreement that all patients who receive a tobacco dependence intervention should be assessed for abstinence at the completion of treatment and during subsequent clinic contacts. PHS and UMHS agree that abstinent patients should have their quitting success acknowledged, be offered assistance with problems associated with quitting, and be educated regarding relapse prevention. PHS and UMHS further agree that patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt and, if so, offered repeated interventions.

Areas of Difference

Pharmacological Treatment During Pregnancy

The groups differ in their recommendations concerning use of pharmacologic therapy for pregnant women. PHS states that there is insufficient evidence to recommend medications for pregnant women. USPSTF found inadequate evidence to evaluate the safety or efficacy of pharmacotherapy during pregnancy. UMHS, in contrast to PHS and USPSTF, notes that cautious use of bupropion with NRT (especially nicotine gum) may be considered after reviewing risks and benefits with the patient.

Environmental Tobacco Smoke (ETS)

There is disagreement regarding the effectiveness of counseling interventions aimed at parents who smoke to limit children's exposure to ETS. PHS recommends that in order to limit children's exposure to secondhand smoke, clinicians should ask parents about tobacco use and offer them cessation advice and assistance. UMHS, in contrast, states that there is mixed evidence to support counseling to reduce ETS exposure in the home. They resume by noting that there is little difference between the well infant, child respiratory illness, and other child illness settings as contexts for parental smoking cessation interventions.

Pharmacological Treatment of Children and Adolescents

Recommendations regarding pharmacological treatment of tobacco dependence in adolescents differ. According to UMHS, until ongoing larger studies addressing this topic are published, NRT or bupropion may be considered for use in adolescent smokers. PHS, in contrast, states that there is insufficient evidence to recommend medications for tobacco dependence treatment to adolescents.

COMPARISON OF RECOMMENDATIONS

SCREENING AND INITIAL INTERVENTIONS

PHS (2008)	*Screen for Tobacco Use* All patients should be asked if they use tobacco and should have their tobacco-use status documented on a regular basis. Evidence has shown that clinic screening systems, such as expanding the vital signs to include tobacco use status or the use of other reminder systems such as chart stickers or computer prompts, significantly increase rates of clinician intervention. **(Strength of Evidence = A)** *Specialized Assessment* Once a tobacco user is identified and advised to quit, the clinician should assess the patient's willingness to quit at this time. **(Strength of Evidence = C)** • If the patient is willing to make a quit attempt at this time, interventions identified as effective in this Guideline should be initiated. (see Chapter 3A and 4 in the original guideline document) • If the patient is unwilling to quit at this time, an intervention designed to increase future quit attempts should be provided. (see Chapter 3B in the original guideline document) Tobacco dependence treatment is effective and should be delivered even if specialized assessments are not used or available. **(Strength of Evidence = A)** *Advice to Quit Smoking* All physicians should strongly advise every patient who smokes to quit because evidence shows that physician advice to quit smoking increases abstinence rates. **(Strength of Evidence = A)** *For Smokers Not Willing to Make a Quit Attempt at This Time* Motivational intervention techniques appear to be effective in increasing a patient's likelihood of making a future quit attempt. Therefore, clinicians should use motivational techniques to encourage smokers who are not currently willing to quit to consider making a quit attempt in the future. **(Strength of Evidence = B)**
UMHS (2006)	**Key Points** **ASK** all patients about smoking status and assess smoker's readiness to quit. Smoking status should be documented in the

	medical record.
	
	ADVISE all smokers to seriously consider making a quit attempt using a clear and personalized message. Advice as brief as 3 minutes is effective ***[A]***.
	
	ASSESS all smokers' willingness to make a quit attempt. If not yet ready to quit, offer motivational intervention using the 5 "R's" – relevance, risks, rewards, roadblocks, repetition.
	
	REFER patients interested in quitting within 30 days to a tobacco treatment specialist or other appropriate tobacco cessation program. Alternatively, health care providers can directly provide the following treatment:
	
	Treatment Options
	
	• **ASSIST** those ready to make a quit attempt:
	  • Set a quit date. Quit date abstinence is a strong predictor of long-term success ***[C]***.
	  • Give advice on quitting and provide supplementary materials.
	  • Prescribe pharmacologic therapy as appropriate. Nicotine replacement therapies, bupropion hydrochloride, and varenicline have been proven effective ***[A]***.
	• **ARRANGE** follow-up either with phone call or office visit.
	  • Prevent relapse by congratulating successes and reinforcing reasons for quitting.
	  • Assess any difficulties with pharmacologic therapy.

USPSTF (2009)	The USPSTF recommends that clinicians ask all adults about tobacco use and provide tobacco cessation interventions for those who use tobacco products. **This is a grade A recommendation.** **Recognition of Behavior** The "5-A" behavioral counseling framework provides a useful strategy for engaging patients in smoking cessation discussions: 1) Ask about tobacco use; 2) Advise to quit through clear personalized messages; 3) Assess willingness to quit; 4) Assist to quit; and 5) Arrange follow-up and support. **Effectiveness of Interventions to Change Behavior** In nonpregnant adults, the USPSTF found convincing evidence that smoking cessation interventions, including brief behavioral counseling sessions (<10 minutes) and pharmacotherapy delivered in primary care settings, are effective in increasing the proportion of smokers who successfully quit and remain abstinent for 1 year.

	Although less effective than longer interventions, even minimal interventions (<3 minutes) have been found to increase quit rates. See the Clinical Considerations section for a discussion of complementary services to which primary care clinicians may refer patients. The USPSTF found convincing evidence that smoking cessation decreases the risk for heart disease, stroke, and lung disease.
TREATMENT **Abbreviations** **Back to TOC**	
Counseling and Behavioral Therapies	
PHS (2008)	**Treatment Structure and Intensity** *Intensity of Clinical Interventions* Minimal interventions lasting less than 3 minutes increase overall tobacco abstinence rates. Every tobacco user should be offered at least a minimal intervention, whether or not he or she is referred to an intensive intervention. **(Strength of Evidence = A)** There is a strong dose-response relation between the session length of person-to-person contact and successful treatment outcomes. Intensive interventions are more effective than less intensive interventions and should be used whenever possible. **(Strength of Evidence = A)** Person-to-person treatment delivered for four or more sessions appears especially effective in increasing abstinence rates. Therefore, if feasible, clinicians should strive to meet four or more times with individuals quitting tobacco use. **(Strength of Evidence = A)** *Type of Clinician* Treatment delivered by a variety of clinician types increases abstinence rates. Therefore, all clinicians should provide smoking cessation interventions. **(Strength of Evidence = A)** Treatments delivered by multiple types of clinicians are more effective than interventions delivered by a single type of clinician. Therefore, the delivery of interventions by more than one type of clinician is encouraged. **(Strength of Evidence = C)** *Formats of Psychosocial Treatments*

	Proactive telephone counseling, group counseling, and individual counseling formats are effective and should be used in smoking cessation interventions. **(Strength of Evidence = A)** Smoking cessation interventions that are delivered in multiple formats increase abstinence rates and should be encouraged. **(Strength of Evidence = A)** **Treatment Elements** *Types of Counseling and Behavioral Therapies* Two types of counseling and behavioral therapies result in higher abstinence rates: (1) providing smokers with practical counseling (problem solving skills/skills training), and (2) providing support and encouragement as part of treatment. These types of counseling elements should be included in smoking cessation interventions. **(Strength of Evidence = B)**

UMHS (2006)	Refer patients interested in quitting within 30 days to a tobacco treatment specialist or other appropriate tobacco cessation program.
	
	Alternatively, health care providers can directly provide the following treatment:
	
	• Consider referral to intensive counseling (multi-session, group or individual). Referral considerations include:
	  • Multiple, unsuccessful quit attempts initiated by brief intervention
	  • Increased need for skill building (coping strategies/problem solving), social support, and relapse prevention
	  • Psychiatric cofactors such as depression, eating disorder, anxiety disorder, attention deficit disorder, or alcohol abuse
	• Give key advice on successful quitting.
	  • **Abstinence**. Total abstinence is essential ***[D]***, not even a single puff after quit date.
	  • **Alcohol**. Drinking alcohol is strongly associated with relapse ***[C]***.
	  • **Other smokers in the household**. The presence of other smokers in the household, particularly a spouse, is associated with lower success rates ***[C]***.
	• Provide supplemental educational materials.
	
	Rationale for Recommendations
	
	Treatment — Counseling

	There is a strong dose response relationship between the intensity of person-to-person contact and successful outcomes ***[A]***. When providing counseling, health care providers should be aware that barriers to smoking cessation include, but are not limited to, severe withdrawal during previous quit attempts, the presence of other smokers in the home or workplace, stressful life circumstances, psychiatric co-morbidities (i.e., depression, alcoholism), multiple quit attempts, and low motivation. Identifying these barriers during initial assessment will help to provide a tailored approach during counseling. In addition to clinician counseling in the office, intensive counseling (frequently defined as a minimum of weekly meeting for the first 4 to 7 weeks of cessation) significantly enhances cessation rates. However, participation in intensive counseling is based largely on patients' motivation to quit ***[C]***. In some locations, if physicians formally refer patients to a tobacco cessation program, a third party may cover the fee with patients paying a reduced or no fee.
USPSTF (2009)	**Counseling Interventions** Various primary care clinicians may deliver effective interventions. There is a dose-response relationship between quit rates and the intensity of counseling (that is, more or longer sessions improve quit rates). Quit rates seem to plateau after 90 minutes of total counseling contact time. Helpful components of counseling include problem-solving guidance for smokers (to help them develop a plan to quit and overcome common barriers to quitting) and the provision of social support as part of treatment. Complementary practices that improve cessation rates include motivational interviewing, assessing readiness to change, offering more intensive counseling or referrals, and using telephone "quit lines."
Pharmacotherapy	
PHS (2008)	**Medication Evidence** Clinicians should encourage all patients attempting to quit to use effective medications for tobacco dependence treatment, except where contraindicated or for specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). **(Strength of Evidence = A)** **Recommendations Regarding Individual Medications: First-Line Medications** First-line medications are those that have been found to be safe and effective for tobacco dependence treatment and that have been approved by the FDA for this use, except in the presence of

contraindications or with specific populations for which there is insufficient evidence of effectiveness (i.e., pregnant women, smokeless tobacco users, light smokers, and adolescents). These first-line medications have an established empirical record of effectiveness, and clinicians should consider these agents first in choosing a medication. For the 2008 update, the first-line medications are listed in Table 6.26 in the original guideline document by size of the odds ratio and in the text alphabetically by generic name.

Bupropion SR

Bupropion SR is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

NRT

Nicotine Gum

Nicotine gum is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

Clinicians should offer 4 mg rather than 2 mg nicotine gum to highly dependent smokers. **(Strength of Evidence = B)**

Nicotine Inhaler

The nicotine inhaler is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

Nicotine Lozenge

The nicotine lozenge is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = B)**

Nicotine Nasal Spray

Nicotine nasal spray is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

Nicotine Patch

The nicotine patch is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence =**

A)

Varenicline

Varenicline is an effective smoking cessation treatment that patients should be encouraged to use. **(Strength of Evidence = A)**

Recommendations Regarding Second-Line Medications

Second-line medications are medications for which there is evidence of effectiveness for treating tobacco dependence, but they have a more limited role than first-line medications because: (1) the FDA has not approved them for a tobacco dependence treatment indication; and (2) there are more concerns about potential side effects than exist with first-line medications. Second-line medications should be considered for use on a case-by-case basis after first line treatments (either alone or in combination) have been used without success or are contraindicated. The listing of the second-line medications is alphabetical by generic name.

Clonidine

Clonidine is an effective smoking cessation treatment. It may be used under a physician's supervision as a second-line agent to treat tobacco dependence. **(Strength of Evidence = A)**

Nortriptyline

Nortriptyline is an effective smoking cessation treatment. It may be used under a physician's supervision as a second-line agent to treat tobacco dependence. **(Strength of Evidence = A)**

Combination Medications

Certain combinations of first-line medications have been shown to be effective smoking cessation treatments. Therefore, clinicians should consider using these combinations of medications with their patients who are willing to quit. Effective combination medications are:

- Long-term (>14 weeks) nicotine patch + other NRT (gum and spray)
- The nicotine patch + the nicotine inhaler
- The nicotine patch + bupropion SR **(Strength of Evidence = A)**

The number and variety of analyzable articles was sufficient to assess the effectiveness of five combinations of medications relative to placebo. Only the patch + bupropion combination has been approved by the FDA for smoking cessation. See the original

	guideline document for evidence regarding the following combinations: • Nicotine patch + bupropion SR • Nicotine patch + nicotine inhaler • Long-term nicotine patch use + *ad libitum* NRT • Nicotine patch + nortriptyline • Nicotine patch + second generation antidepressants **Medications Not Recommended by the Guideline Panel** • Antidepressants other than bupropion SR and nortriptyline • Selective serotonin re-uptake inhibitors (SSRIs) • Anxiolytics/benzodiazepines/beta-blockers • Opioid antagonists/naltrexone • Silver acetate • Mecamylamine • Extended use of medications • Use of NRT in cardiovascular patients **Use of Over-the-Counter Medications** Over-the-counter nicotine patch therapy is more effective than placebo, and its use should be encouraged. **(Strength of Evidence = B)** **Other Specific Populations and Topics** *Weight Gain After Smoking Cessation* For smokers who are greatly concerned about weight gain, it may be most appropriate to prescribe or recommend bupropion SR or NRT (in particular nicotine gum and nicotine lozenge), which have been shown to delay weight gain after quitting. **(Strength of Evidence = B)**
UMHS (2008)	**Treatment — Pharmacologic Therapies** NRT, bupropion hydrochloride (Zyban), and varenicline (Chantix®) have been shown to significantly improve cessation rates ***[A]***. Therefore, pharmacologic therapy should be recommended to all patients except in the presence of specific contraindications. Bupropion and varenicline are the two non-nicotine products with FDA approval for smoking cessation. Non-FDA approved agents with potential benefit in smoking cessation include nortriptyline and clonidine. These drugs may best be used as second-line agents when patients cannot take or do not wish to take either NRT, bupropion, or varenicline ***[D]***.

NRT

The various NRTs significantly decrease symptoms of the withdrawal syndrome as smokers abruptly stop smoking ***[A]***.

In very highly dependent smokers, 4 mg gum is superior to 2 mg and most effective with counseling ***[A]***. High dose patch therapy (i.e., 44 mg/24 hr = two patches) is safe and decreases withdrawal symptoms in highly dependent smokers, but does not increase long term cessation rates ***[A]***. Those smoking 5 or fewer cigarettes per day have been shown to have few symptoms of nicotine withdrawal when they quit ***[C]*** and may not require NRT ***[D]***.

For those using nicotine gum, spray or inhaler, it is important that they are instructed in technique and dosing frequency so that underdosing does not occur. See Table 4 in the original guideline document for dosing and administration recommendations. The patient should also be provided with the educational handout, "How to Use Your Nicotine Product."

Combining NRTs

Given the additional cost of dual therapies (e.g., patch plus gum; patch plus inhaler; patch plus nasal spray) and limited benefit, combining NRT is best reserved for highly addicted smokers with several previous failed quit attempts ***[D]***.

Patients with Cardiovascular Disease

The patch and nasal spray have demonstrated safety in patients with stable coronary artery disease ***[A]***. While patients should be reminded not to smoke while using these products, studies have shown no increase in cardiac event rates when patients smoke while wearing the patch ***[C]***.

Choosing between Bupropion Hydrochloride or Nicotine Replacement

A single trial sponsored by the manufacturer of Zyban suggests that bupropion may be superior to nicotine patch therapy ***[A]***. Given this single study, it remains reasonable to consider patient preferences, previous quit attempt experiences and cost when choosing among pharmacologic therapies ***[D]***.

For smokers who have previously been unsuccessful, one randomized study showed higher success rates for both bupropion alone or in combination with the nicotine patch, compared to nicotine patch alone ***[A]***.

USPSTF (2009)	**Treatment** Pharmacotherapy approved by the U.S. Food and Drug Administration and identified as effective for treating tobacco dependence in nonpregnant adults includes several forms of NRT (gum, lozenge, transdermal patch, inhaler, and nasal spray), sustained-release bupropion, and varenicline.
Combined Psychosocial and Pharmacological Interventions	
PHS (2008)	*Combining Counseling and Medication* The combination of counseling and medication is more effective for smoking cessation than either medication or counseling alone. Therefore, whenever feasible and appropriate, both counseling and medication should be provided to patients trying to quit smoking. **(Strength of Evidence = A)** There is a strong relation between the number of sessions of counseling, when it is combined with medication, and the likelihood of successful smoking cessation. Therefore, to the extent possible, clinicians should provide multiple counseling sessions, in addition to medication, to their patients who are trying to quit smoking. **(Strength of Evidence = A)**
UMHS (2006)	The efficacy of all forms of NRT is improved with concomitant counseling, but there is evidence for the effectiveness of NRT, even in the absence of counseling. In very highly dependent smokers, 4 mg gum is superior to 2 mg and most effective with counseling ***[A]***.
USPSTF (2009)	**Treatment** Combination therapy with counseling and medications is more effective at increasing cessation rates than either component alone.
CONSIDERATIONS IN SPECIAL POPULATIONS Abbreviations Back to TOC	
Pregnant Women	
PHS (2008)	**Other Specific Populations and Topics** *Pregnant Smokers* Because of the serious risks of smoking to the pregnant smoker and the fetus, whenever possible pregnant smokers should be offered

	person-to-person psychosocial interventions that exceed minimal advice to quit. **(Strength of Evidence = A)** Although abstinence early in pregnancy will produce the greatest benefits to the fetus and expectant mother, quitting at any point in pregnancy can yield benefits. Therefore, clinicians should offer effective tobacco dependence interventions to pregnant smokers at the first prenatal visit as well as throughout the course of pregnancy. **(Strength of Evidence = B)**
UMHS (2006)	**Pregnant Patients** Intensive counseling interventions increase quit rates during pregnancy ***[A]***. If intensive counseling is not possible, brief in-office counseling still has a beneficial effect and should be offered. Few studies have addressed the safety of NRT or bupropion in pregnancy directly; however, studies show that less nicotine and fewer metabolites cross the placenta with the use of NRT than with smoking itself. Therefore cautious use of bupropion with NRT (especially nicotine gum) may be considered after reviewing risks and benefits with the patient. **Breastfeeding Women** Smoking leads to a significant reduction in breast milk volume and increases the likelihood of early discontinuation ***[A]***. Data support the use of bupropion plus NRT in nursing mothers, with increased cessation rates. The safety profile is favorable, as less nicotine and fewer metabolites are found in breast milk with NRT, compared to smoking more than a half a pack per day. Additionally, eliminating environmental exposure to the infant is a favorable outcome. It is not known whether varenicline is excreted in human milk.
USPSTF (2009)	The USPSTF recommends that clinicians ask all pregnant women about tobacco use and provide augmented, pregnancy-tailored counseling for those who smoke. **This is a grade A recommendation.** **Effectiveness of Interventions to Change Behavior** In pregnant women, the USPSTF found convincing evidence that smoking cessation counseling sessions, augmented with messages and self-help materials tailored for pregnant smokers, increases abstinence rates during pregnancy compared with brief, generic counseling interventions alone. Tobacco cessation at any point during pregnancy yields substantial health benefits for the expectant mother and baby. The USPSTF found inadequate evidence to evaluate the safety or efficacy of pharmacotherapy during pregnancy.

Children and Adolescents	
PHS (2008)	*Children and Adolescents* Clinicians should ask pediatric and adolescent patients about tobacco use and provide a strong message regarding the importance of totally abstaining from tobacco use. **(Strength of Evidence = C)** Counseling has been shown to be effective in treatment of adolescent smokers. Therefore, adolescent smokers should be provided with counseling interventions to aid them in quitting smoking. **(Strength of Evidence = B)** Secondhand smoke is harmful to children. Cessation counseling delivered in pediatric settings has been shown to be effective in increasing abstinence among parents who smoke. Therefore, to protect children from secondhand smoke, clinicians should ask parents about tobacco use and offer them cessation advice and assistance. **(Strength of Evidence = B)**
UMHS (2006)	**Treatment — Counseling** The evidence for the effectiveness of counseling in adolescent smokers is less robust. However, some studies demonstrate that smoking cessation counseling in the primary care setting can improve adolescent smokers' quit rates ***[A]***. There is little difference between the well infant, child respiratory illness, and other child illness settings as contexts for parental smoking cessation interventions ***[B]***. **Treatment — Pharmacologic Therapies** The utility of pharmacologic therapy for adolescents has been examined in a number of small studies. While the evidence indicates that these therapies are safe, they seem to be more effective when coupled with counseling. Additional, larger trials are ongoing to evaluate this issue. In the meantime, NRT or bupropion may be considered for use in adolescent smokers ***[D]***.
USPSTF (2009)	No recommendations offered. The USPSTF plans to issue a separate recommendation statement about counseling to prevent tobacco use in nonpregnant adolescents and children.
Other Special Populations	

PHS (2008)	**Special Populations and Other Topics** The interventions found to be effective in this Guideline have been shown to be effective in a variety of populations. In addition, many of the studies supporting these interventions comprised diverse samples of tobacco users. Therefore, interventions identified as effective in this Guideline are recommended for all individuals who use tobacco, except when medication use is contraindicated or with specific populations in which medication has not been shown to be effective (pregnant women, smokeless tobacco users, light smokers, and adolescents). **(Strength of Evidence = B)** See the original guideline document for a discussion of clinical issues for specific populations, including HIV-positive smokers; hospitalized smokers; lesbian/gay/bisexual/transgender (LGBT) smokers; smokers with low socioeconomic status (SES)/limited formal education; smokers with comorbid conditions, including cancer, cardiac disease, chronic obstructive pulmonary disease (COPD), diabetes, and asthma; older smokers; smokers with psychiatric disorders, including substance use disorders; racial and ethnic minority populations, and women. **Other Specific Populations and Topics** *Light Smokers* *Light smokers should be identified, strongly urged to quit, and provided counseling cessation interventions.* ***(Strength of Evidence = B)*** *Noncigarette Tobacco Users* *Smokeless tobacco users should be identified, strongly urged to quit, and provided counseling cessation interventions.* ***(Strength of Evidence = A)*** *Clinicians delivering dental health services should provide brief counseling interventions to all smokeless tobacco users.* ***(Strength of Evidence = A)*** *Users of cigars, pipes, and other noncigarette forms of smoking tobacco should be identified, strongly urged to quit, and offered the same counseling interventions recommended for cigarette smokers.* ***(Strength of Evidence = C)***
UMHS (2006)	*Racial and Ethnic Minorities* Smoking cessation treatment has been shown to be effective across both racial and ethnic minorities ***[A]***. Little research has examined intervention specifically designed for a particular ethnic or racial

group; however, it is recommended that, when possible, smoking cessation treatment should be tailored to the specific ethnic or racial population with which they are used ***[C]***. It is essential that counseling or self-help materials be conveyed in a language understood by the smoker.

Psychiatric Cofactors

If presence of psychiatric cofactors, such as depression, eating disorder, anxiety disorder, attention deficit disorder, or alcohol abuse, strongly consider referral to intensive counseling ***[B]***. Treatment of cofactors must be undertaken in preparation for smoking cessation.

Non-cigarette Tobacco Users

Spit tobacco users should be identified and strongly urged to quit tobacco use, using the same counseling interventions recommended for smokers ***[A]***. The clinicians should provide a clear message that the use of spit tobacco is not a safe alternative to smoking. Use of cigars, pipes, and other non-cigarette combustible forms of tobacco should be identified, strongly urged to quit, and offered the same counseling interventions recommended for smokers ***[C]***.

Gender Concerns

Smoking cessation treatments are shown to benefit both women and men [B]. Two studies suggest that some treatments are less efficacious in women than in men. Women may face different stressors and barriers to quitting (e.g., greater likelihood of depression, greater weight control concerns, and hormonal cycles). This research suggests cessation programs that address these issues would be more effective in treating women ***[D]***.

Older Smokers

Smoking cessation treatment has been shown to be effective for older adults and should be provided, as cessation improves pulmonary function and cerebral circulation ***[A]***. Several studies have found cessation rates among motivated older adults similar to those for younger adults; however, supportive counseling and social support may be of more value to prevent relapse than education or skills training ***[A]***.

Hospitalized Smokers

Providing hospitalized patients with high-intensity behavioral counseling and follow-up of at least 30 days has been shown to increase cessation rates ***[A]***. NRT supplementation can also be useful in this population. Briefer interventions (<20 minutes,

	delivered only during the hospitalization) have not yet been shown to be helpful. Additional treatment can include self-help brochures or audio/video tapes, chart prompts reminding physicians to advise for cessation, pharmacologic therapy, hospital counseling, and post-discharge counseling telephone calls. Hospitalization should be used as a springboard to promote smoking cessation.
USPSTF (2009)	No recommendations offered.
FOLLOW-UP AND RELAPSE PREVENTION **Abbreviations** **Back to TOC**	
PHS (2008)	*Follow-up Assessment and Procedures* All patients who receive a tobacco dependence intervention should be assessed for abstinence at the completion of treatment and during subsequent clinic contacts. (1) Abstinent patients should have their quitting success acknowledged, and the clinician should offer to assist the patient with problems associated with quitting (see Chapter 3C, For the Patient Who Has Recently Quit, in the original guideline document). (2) Patients who have relapsed should be assessed to determine whether they are willing to make another quit attempt. **(Strength of Evidence = C)**: • If the patient is willing to make another quit attempt, provide or arrange additional treatment (see Chapter 3A, For the Patient Willing To Quit, in the original guideline document.) If the patient is not willing to try to quit, provide or arrange an intervention designed to increase future quit attempts (see Chapter 3B, For the Patient Unwilling To Quit, in the original guideline document).
UMHS (2006)	Arrange follow-up either with phone call or office visit. Follow-up contact should occur soon after the quit date, preferably during the first week ***[C]***. Extending treatment contacts over a number of weeks appears to increase cessation rates ***[D]***. Further follow-up as needed. For abstinent patients, prevent relapse by • Congratulate successes and stress importance of remaining abstinent. • Review benefits to be derived from quitting. • Inquire regarding problems encountered and offer possible solutions to maintaining abstinence.

	For smoking patients: • Review circumstances and elicit re-commitment to total abstinence. • Remind patients that a lapse can be used as a learning experience. • Identify problems, suggest alternative behaviors and anticipate challenges in the immediate future. • Re-assess choice of pharmacologic interventions as needed. • Consider referral to a more intense or specialized program.
USPSTF (2009)	No specific recommendations offered.
EDUCATION **Abbreviations** **Back to TOC**	
PHS (2008)	**Treatment Structure and Intensity** *Formats of Psychosocial Treatments* Tailored materials, both print and Web-based, appear to be effective in helping people quit. Therefore, clinicians may choose to provide tailored self-help materials to their patients who want to quit. **(Strength of Evidence = B)**
UMHS (2006)	**Information the Patient Needs to Know** **Supplementary materials**. The UMHS produces two useful patient education handouts: • How to use your nicotine product • Tips for quitting smoking Additionally, the National Cancer Institute produces the pamphlet "Clearing the Air" (NIH Pub. 03-1647). You may obtain 20 free copies at a time by calling 1-800-4-CANCER (1-800-422-6237). It is also available online at http://www.smokefree.gov/pubs/clearing_the_air.pdf. **Preparation and effects**. Review with patients the following additional information about preparing for quitting and related factors. • **Review handout(s)**. The handout(s) provide many useful tips to help you with your quit attempt. Read these and make plans before your quit attempt.

	• **NRT/bupropion/varenicline**. NRT, bupropion, and varenicline are most effective when used correctly. If you have any uncertainties about proper use, this should be clarified. • **Caffeine**. You are likely to perceive greater effects from your usual caffeine consumption after you quit smoking and may need to decrease your intake. • **Theophylline**. If you take theophylline, levels should be checked approximately 2 weeks after you quit smoking.
USPSTF (2009)	No specific recommendations offered.

STRENGTH OF EVIDENCE AND RECOMMENDATION GRADING SCHEMES

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PHS (2008)

Strength of Evidence Grades

A. Multiple well-designed randomized clinical trials, directly relevant to the recommendation, yielded a consistent pattern of findings.
B. Some evidence from randomized clinical trials supported the recommendation, but the scientific support was not optimal. For instance, few randomized trials existed, the trials that did exist were somewhat inconsistent, or the trials were not directly relevant to the recommendation.
C. Reserved for important clinical situations in which the Panel achieved consensus on the recommendation in the absence of relevant randomized controlled trials.

UMHS (2006)

Levels of evidence reflect the best available literature in support of an intervention or test:

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

USPSTF (2009)

What the United States Preventive Services Task Force (USPSTF) Grades Mean and Suggestions for Practice

Grade	Grade Definitions	Suggestions for Practice
A	The USPSTF recommends the service. There is high	Offer or provide this service.

	certainty that the net benefit is substantial.	
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer or provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I Statement	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	Read the "Clinical Considerations" section of the USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms (see "Major Recommendations" field).

USPSTF Levels of Certainty Regarding Net Benefit

Definition: The U.S. Preventive Services Task Force defines certainty as "likelihood that the USPSTF assessment of the net benefit of a preventive service is correct." The net benefit is defined as benefit minus harm of the preventive service as implemented in a general, primary care population. The USPSTF assigns a certainty level based on the nature of the overall evidence available to assess the net benefit of a preventive service.

Level of Certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is

	therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by factors such as: • The number, size, or quality of individual studies • Inconsistency of findings across individual studies • Limited generalizability of findings to routine primary care practice • Lack of coherence in the chain of evidence As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies • Important flaws in study design or methods • Inconsistency of findings across individual studies • Gaps in the chain of evidence • Findings not generalizable to routine primary care practice • A lack of information on important health outcomes More information may allow an estimation of effects on health outcomes.

COMPARISON OF METHODOLOGY
Click on the links below for details of guideline development methodology

PHS (2008)	**UMHS (2006)**	**USPSTF (2009)**

Methods to collect and select the evidence were similar, with all three groups performing searches of electronic databases and hand searches of published literature (primary sources). UMHS also performed hand searches of published sources (secondary sources). PHS and UMHS specify the date range that was searched, January 1999–January 2007 and January 1999–January 2005, respectively. Both also provide search terms used inclusion/exclusion criteria that were applied. USPSTF only reviewed the 2008 PHS guideline and found no new substantial evidence that could change its recommendations. It therefore reaffirms its previous recommendations.

To assess the quality and strength of the evidence, PHS and UMHS used weighting

according to a rating scheme, while USPSTF utilized expert consensus. Methods used to analyze the evidence differ. All of the groups performed some variation of a review. Both UMHS and PHS performed a systematic review; the PHS systematic review incorporated evidence tables. Moreover, UMHS and USPSTF both performed a review of published meta-analyses, while PHS conducted its own meta-analysis of randomized controlled trials. PHS and UMHS provide a description of the evidence analysis process. With regard to formulation of guideline recommendations, all three groups used expert consensus; USPSTF also used balance sheets. PHS and USPSTF provide a description of the guideline formulation process. USPSTF is the only group to grade its recommendations according to a rating scheme. Neither UMHS nor USPSTF performed a formal cost analysis or reviewed published cost analyses. PHS, in contrast, provides detailed information regarding the cost-effectiveness of tobacco use treatment recommendations in chapter 6 of the original guideline document. All three groups used some variation of peer review as a method of guideline validation; USPSTF also compared its recommendations with those of other groups. All of the groups provide a description.

SOURCE(S) OF FUNDING Abbreviations Back to TOC	
PHS (2008)	United States Government
UMHS (2006)	University of Michigan Health System
USPSTF (2009)	United States Government

BENEFITS AND HARMS Abbreviations Back to TOC	
Benefits	
PHS (2008)	Appropriate assessment and treatment of tobacco use and dependence
UMHS	Effective interventions and strategies for health care providers to assist

(2006)	patients in smoking cessation
USPSTF (2009)	**Effectiveness of Interventions to Change Behavior** • In nonpregnant adults, the USPSTF found convincing evidence that smoking cessation interventions, including brief behavioral counseling sessions (<10 minutes) and pharmacotherapy delivered in primary care settings, are effective in increasing the proportion of smokers who successfully quit and remain abstinent for 1 year. Although less effective than longer interventions, even minimal interventions (<3 minutes) have been found to increase quit rates. • The USPSTF found convincing evidence that smoking cessation decreases the risk for heart disease, stroke, and lung disease. • In pregnant women, the USPSTF found convincing evidence that smoking cessation counseling sessions, augmented with messages and self-help materials tailored for pregnant smokers, increases abstinence rates during pregnancy compared with brief, generic counseling interventions alone. Tobacco cessation at any point during pregnancy yields substantial health benefits for the expectant mother and baby. The USPSTF found inadequate evidence to evaluate the safety or efficacy of pharmacotherapy during pregnancy. **USPSTF Assessment** • The USPSTF concludes that there is high certainty that the net benefit of tobacco cessation interventions in adults is substantial. • The USPSTF also concludes that there is high certainty that the net benefit of augmented, pregnancy-tailored counseling in pregnant women is substantial.
Harms	
PHS (2008)	• Weight gain related to cessation of tobacco use • Exacerbation of comorbid psychiatric conditions following cessation of tobacco use • Side effects of pharmacological agents approved by the U.S. Food and Drug Administration (FDA) for smoking cessation: *Bupropion SR*: The most common side effects reported were insomnia (35% to 40%) and dry mouth (10%). *Nicotine chewing gum*: Common side effects include mouth soreness, hiccups, dyspepsia, and jaw ache. These effects are generally mild and transient, and often can be alleviated by correcting the patient's chewing technique.

Nicotine inhaler: Local irritation in the mouth and throat was observed in 40% of patients using the nicotine inhaler. Coughing (32%) and rhinitis (23%) also were common. Severity was generally rated as mild, and the frequency of such symptoms declined with continued use.

Nicotine lozenge: The most common side effects are nausea, hiccups, and heartburn. Individuals on the 4-mg lozenge also had increased rates of headache and coughing (less than 10% of participants).

Nicotine nasal spray:

- Nasal/airway reactions. Some 94% of users report moderate to severe nasal irritation in the first 2 days of use; 81% still reported nasal irritation after 3 weeks, although rated severity was mild to moderate. Nasal congestion and transient changes in sense of smell and taste were also reported. Nicotine nasal spray should not be used in persons with severe reactive airway disease.
- Dependency. Nicotine nasal spray has a dependence potential intermediate between other nicotine-based therapies and cigarettes. About 15% to 20% of patients report using the active spray for longer periods than recommended, and 5% used the spray at a higher dose than recommended.

Nicotine patch: Up to 50% of patients using the nicotine patch will have a local skin reaction. Skin reactions are usually mild and self-limiting, but occasionally worsen over the course of therapy. Local treatment with hydrocortisone cream (1%) or triamcinolone cream (0.5%) and rotating patch sites may ameliorate such local reactions. In fewer than 5% of patients, such reactions require the discontinuation of nicotine patch treatment. Other side effects include insomnia and/or vivid dreams.

Varenicline: Nausea, trouble sleeping, abnormal/vivid/strange dreams

- Side effects of pharmacologic agents not FDA approved for smoking cessation:

Clonidine: Most commonly reported side effects include dry mouth (40%), drowsiness (33%), dizziness (16%), sedation (10%), and constipation (10%). As an antihypertensive medication, clonidine can be expected to lower blood pressure in most patients. Therefore, clinicians may need to monitor blood pressure when using this medication. Rebound hypertension may occur if the dose is not gradually reduced over a period of 2 to 4 days (rapid increase in blood pressure, agitation, confusion, and/or tremor

	may occur). *Nortriptyline*: Most commonly reported side effects include sedation, dry mouth (64% to 78%), blurred vision (16%), urinary retention, lightheadedness (49%), and shaky hands (23%). See the tables in Chapter 3 of the original guideline documents for additional information, including precautions when using medications in pregnant smokers or those with cardiovascular disease. Also see Chapter 6 in the original guideline document for information about interactions of first-line tobacco use medications with other drugs.
UMHS (2006)	Side effects of medications may occur and include the following: • *Nicotine Lozenge* — Headache, diarrhea, flatulence, heartburn, hiccups, nausea, coughing, sore throat, and upper respiratory infection (occurring in >5% of patients) • *Transdermal Nicotine Patch* — Skin reactions such as pruritus, edema, rash; sleep disturbance • *Nicotine Gum (Polacrilex)* — Jaw fatigue, hiccups, belching, and nausea • *Nicotine Nasal Spray* — Nasal irritation/rhinorrhea (98% of patients), sneeze, cough • *Nicotine Inhaler* — Cough, mouth and throat irritation • *Bupropion Hydrochloride SR (Zyban®)* and *Bupropion Hydrochloride* — Insomnia, dry mouth, nausea, and seizures. It should be used with caution in patients with predisposition to seizure (i.e., head trauma, alcohol withdrawal, concomitant use with other medications that lower seizure threshold — antipsychotics, antidepressants, theophylline) • *Varenicline (Chantix®)* — Nausea, insomnia, and unusual dreams; should not be used in conjunction with NRT products • *Clonidine* — Dry mouth and sedation • *Nortriptyline* — Dry mouth Few studies have addressed the safety of nicotine replacement therapy or bupropion in pregnancy directly; however, studies show that less nicotine and fewer metabolites cross the placenta with the use of nicotine replacement therapy than with smoking itself. The U.S. Food and Drug Administration (FDA) pregnancy risk categories are: bupropion — category B, nicotine transdermal, spray and inhaler — category D, nicotine gum — category C, varenicline — category C. Most smokers who quit will gain weight, but the majority will gain less than 10 pounds.
USPSTF (2009)	**Harms of Interventions** Finding no published studies that describe harms of counseling to prevent tobacco use in adults or pregnant women, the USPSTF judged

	the magnitude of these harms to be no greater than small. Harms of pharmacotherapy are dependent on the specific medication used. In nonpregnant adults, the USPSTF judged these harms to be small.

CONTRAINDICATIONS Abbreviations Back to TOC	
PHS (2008)	Bupropion SR: This agent is contraindicated in individuals with a history of seizures or eating disorders, who are taking another form of bupropion, or who have used a MAO inhibitor in the past 14 days.
UMHS (2006)	Bupropion hydrochloride and Bupropion hydrochloride SR (Zyban®) are contraindicated in patients with seizure disorder, major head trauma, eating disorders, and in patients on Wellbutrin® or MAO inhibitors.
USPSTF (2009)	Not stated

Abbreviations
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ETS, environmental tobacco smoke

FDA, Food and Drug Administration

MAO, monoamine oxidase

NRT, nicotine replacement therapy

PHS, Public Health Service

SR, sustained release

TTS, tobacco treatment specialist

UMHS, University of Michigan Health System

USPSTF, U.S. Preventive Services Task Force

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